REMARKS

This paper is filed in response to the Final Office Action mailed December 1, 2009. Claims 1-9, 20-26, 34-38, 75, and 76 were considered by the Examiner, Claims 10-19, 27-33, 48-72, and 74 having been previously withdrawn. In this paper, Claim 1 has been amended, Claims 15, 48-72, and 74 have been canceled, and new Claims 77-89 have been added. Additionally, the Specification has been amended to further reflect the drawings as-filed. Accordingly, Claims 1-9, 20-26, 34-38, and 75-89 are presented herein for consideration. No new matter has been added in these amendments.

Summary of the Office Action

In the Office Action, Claims 1-9, 20-24, 34-38, 75, and 76 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine (US Patent No. 6,520,939), in view of Steigerwald (U.S. Patent No. 4,895,346). Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Steigerwald further in view of Green et al. (U.S. Patent No. 6,497,716). For at least the reasons discussed below, Applicant respectfully traverses these rejections.

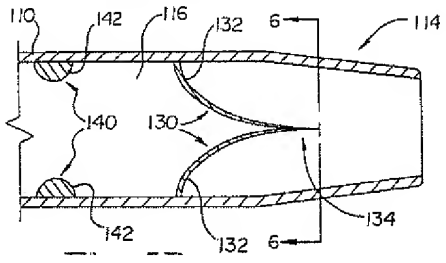
The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine and Steigerwald.

As noted above, in the Office Action, Claims 1-9, 20-24, 34-38, and 75-76 were

rejected under 35 U.S.C. § 103(a) as being anticipated by Lafontaine in view of Steigerwald. For at least the reasons discussed below, Applicant respectfully traverses these rejections.

Lafontaine relates to a hemostasis valve for use with vascular introducer sheaths, catheters, Y-adapters, and the like. (Lafontaine, col. 1, lines 6-9). As illustrated in Figure 5A, reproduced below, Lafontaine describes an introducer sheath including an active hemostasis valve 130 and a passive hemostasis valve 140. (Lafontaine, col. 4, lines 6-7). The active hemostasis valve 130 comprises a plurality of leaflets or flaps 132. (Lafontaine, col. 4, lines 30-31). The passive hemostasis valve 140 is normally open to allow devices to freely pass therethrough, and comprises a flexible polymeric O-ring sized to create either an interference fit or a gap fit with a device inserted therethrough. (Lafontaine, col. 4, lines 47-64).

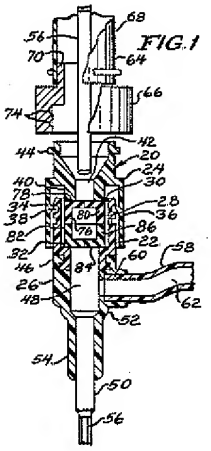
Fig. 5A



Lafontaine teaches away from using a "gasket" seal comprising a disk with the device disclosed therein. In connection with the background to the Lafontaine device, Lafontaine does describe a "gasket" comprising a "disc of flexible polymeric material having" a hole or slit therethrough. (See, e.g., Lafontaine, col. 1, lines 27- 41, Figures

2A, 2B). However, Lafontaine describes these gasket configurations only in relation to admitted prior art vascular access systems that, unlike the access device recited in Claim 1, do not include another seal. Furthermore, Lafontaine emphasizes perceived undesirable performance characteristics of each of these gasket configurations to assert the desirability of the O-ring. (Lafontaine, col. 1, lines 42-55). Thus, Lafontaine teaches away from using one of the described gaskets as either an active hemostasis valve or a passive hemostasis valve in the described surgical access device.

Steigerwald relates to a valve assembly 20 having a hollow body member 22, a compression member 24, and two elastic valve members received in a cavity 28 at the proximal end of the body member 22. (Steigerwald, col. 2, lines 32-35, col. 3, lines 13-19). The elastic valve members each *have a disc with slits formed therein* and an annular rim. (Steigerwald, col. 3, lines 12-26). Figure 1 of Steigerwald, reproduced below, illustrates Steigerwald device.



In contrast to the Lafontaine and Steigerwald devices, Claim 1 relates to a

surgical access device comprising, among other recitations, an elongate tubular member, a septum seal integrally formed at the distal end of the tubular member, and a zero seal disposed at the distal end of the tubular member and distal to the septum seal. The septum seal comprises, among other limitations, "an elastomeric sheet having a frusto-conical shape and an orifice through the elastomeric sheet."

-- The Applied Combination of References Fails to Disclose All of the Recitations of Claim 1.

As discussed above, Lafontaine fails to disclose a septum seal having as recited in Claim 1. Rather, Lafontaine describes an O-ring positioned in an elongate shaft to provide sealing under certain conditions. While Lafontaine does indicate that the O-ring can be "an integral part" of the device as opposed to a releasably connected assembly, Lafontaine fails to disclose or suggest that the O-ring is integrally formed with the tubular structure. (Lafontaine, col. 4, lines 13-22). Instead, Lafontaine illustrates the O-ring with hatching to indicate it is a "juxtaposed different element" with respect to the sheath, even though the valve of Figure 5A is expressly indicated to be an "integral part" of the sheath. (Lafontaine, col. 4, lines 18-22; 37 C.F.R. § 1.84(h)(3)). Thus, Lafontaine has disclosed an O-ring that has been separately formed and later integrated with the sheath, but not the recited "integrally formed" device.

Steigerwald fails to remedy to the deficiencies of Lafontaine with respect to Claim 1. For example, Steigerwald fails to disclose a septum seal that has a frusto-

conical shape or that is "integrally formed" at the distal end of a tubular member. Rather, as discussed above, in the Steigerwald device, two separate valve members comprising discs are positioned within a cavity at the proximal end of a valve assembly. The valve members are compressible with respect to the cavity of the valve assembly by a compression member. Thus, the Steigerwald valve members are not "integrally formed," nor positioned at the distal end of the tubular member, as recited in Claim 1.

-- One Skilled in the Art Would Be Dissuaded by Lafontaine from Incorporating a Valve Member from the Steigerwald Device Therein.

As discussed above, Lafontaine fails to disclose all of the elements of the recited surgical access device. For example, Lafontaine fails to disclose a septum seal comprising an elastomeric sheet having a frusto-conical shape and an orifice through the elastomeric sheet, as is recited in Claim 1. Furthermore, one skilled in the art would be dissuaded by Lafontaine from modifying the device therein to include a valve member as described in the Steigerwald. Rather, as discussed above, Lafontaine teaches away from the use of a disk-shaped "gasket" similar to the valve members of Steigerwald, repeatedly emphasizing the perceived disadvantages of these valve members. In contrast to indication in the Office Action that the valve member (76) of Steigerwald is not a disk-shaped gasket, Steigerwald describes the first valve member as "having a circular disc 78." (Steigerwald, col. 3, lines 12-16). Thus, even though the disc-based valves of Steigerwald also include annular members, one skilled in the art

would expect the disadvantages perceived by Lafontaine to accompany the Steigerwald disc-based valve member.

Accordingly, for at least the reasons discussed above, Claim 1 is distinguishable over the applied art. Claims 2-9, 20-24, 34-38, and 74-76 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. Therefore, Claims 2-9, 20-24, 34-38, and 74-76 are distinguishable over the applied art for at least the reasons discussed above with respect Claim 1.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Steigerwald, and Green.

As noted above, Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine and Steigerwald in view of Green et al. Claims 25 and 26 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. As discussed above, the applied combination of Lafontaine and Steigerwald fails to disclose or suggest all of the limitations of Claim 1. Green appears to have been relied on in the Office Action solely for its asserted disclosure of a specific shape of certain portions of a placement device. Green thus fails to disclose or suggest the deficiencies of Lafontaine and Steigerwald with respect to Claim 1.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 1, from which

Claims 25 and 26 depend. Therefore, at least for the reasons that Claim 1 is distinguishable over the applied combination of references, Claims 25 and 26 are distinguishable over the applied combination of references.

New Claims 77-89

New Claims 77-89 are presented herein for consideration. These new claims relate to the elected species and each include recitations not disclosed or suggested in the applied art. For example, Claim 77 recites a surgical access device comprising, among other limitations, a duckbill valve comprising: opposing lip portions; two crossing slits separating the opposing lip portions; and an occlusive material attached to the opposing lip portions. None of Lafontaine, Steigerwald, and Green disclose a duckbill valve having opposing lip portions with "an occlusive material attached" thereto as recited in Claim 77. Claims 78-83 depend from Claim 77 and recite additional novel and nonobvious limitations thereon. Accordingly, Claims 78-83 are distinguishable over the applied art at least because they depend from a distinguishable base claim.

Claim 84 recites a surgical access device comprising a seal system at the distal end of the tubular member, the seal system comprising a septum seal comprising a septum having an orifice sized and configured to seal in conjunction with a specific range of usable instruments; and a zero seal coupled to the septum seal. None of Lafontaine, Steigerwald, and Green disclose or suggest a device comprising a seal system as recited in Claim 84, and for at least the reasons discussed above, Lafontaine

teaches away from modifying the disclosed O-ring thereof. Claims 85-89 depend from Claim 84 and recite additional novel and nonobvious limitations thereon. Accordingly, Claims 85-89 are distinguishable over the applied art at least because they depend from a distinguishable base claim.

Conclusion

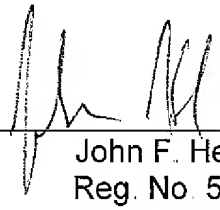
For at least the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowability is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, John F. Heal, at (949) 713-8283 to resolve such issues promptly.

Respectfully Submitted,

APPLIED MEDICAL RESOURCES

BY 

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